

REMARKS

Claims 1-29 constitute the pending claims in the present application. Applicants have amended claims 1 and 20 as discussed below. Applicants have added new claims 26-29. Support for new claims 26 and 27 can be found on page 5, lines 7-11 of the specification as originally filed. Support for new claims 27 and 28 can be found in Sections 2.8 and 2.9 on pages 53-55 and in figure legend 4a on pages 6-7 of the specification as originally filed. Applicants assert these amendments present no new matter.

Claims 3-4, 6, 11, 14-16, 19, and 23-25 were withdrawn as being drawn to nonelected inventions. Applicants disagree that claim 19 is directed to a nonelected invention and submit that claim 19 should be included in Group I (i.e., as defined in the Restriction Requirement mailed July 21, 2009).¹ As with the remaining claims of Group I currently under consideration, claim 19 is drawn to a polymeric particle comprising a pharmaceutically acceptable polymer core, a bioactive agent, and a surface-altering agent disposed on the surface of the core that renders the surface of the polymeric particle mucus resistant and/or enhances the average rate at which the particles or a fraction of the particles moves in mucus, wherein the bioactive agent is encapsulated in the polymer core. Accordingly, Applicants request claim 19 be considered with the remainder of the claims from Group I.

Applicants expressly reserve the right to prosecute claims of similar or differing scope. Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Office will be addressed below in the order they appear in the prior Office Action.

Rejection based on 35 U.S.C. § 102(e). Claims 1-2, 7-8, 13, 17, 20, and 21 are rejected under 35 U.S.C. § 102(e), as allegedly being anticipated by Alavattam et al. (U.S. Patent No. 7,060,299; "Alavattam"). Specifically, the Office argues that the microparticles disclosed in Alavattam anticipate the claimed invention. Applicants traverse this rejection.

¹ In fact, the Office included claim 19 with Group I in both the Restriction Requirement mailed July 21, 2009 and the Restriction Requirement mailed March 4, 2010.

As an initial point, Applicants respectfully submit that a proper anticipation rejection requires that, "The identical invention must be shown in as complete detail as is contained in the... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The Office has failed to show that Alavattam discloses each and every element of the rejected claims. In particular, the Office makes no mention of Alavattam teaching the enhancement of the rate at which the particles or a fraction of the particles move in mucus, a required element of the rejected claims. Accordingly, Applicants respectfully submit the rejection is unsupported and improper.

Nevertheless, solely to expedite prosecution and without acquiescing to the Office's position, Applicants have amended claims 1 and 20 (and claims dependent thereon) to be directed to particular embodiments of the present invention. In particular, Applicants have amended claim 1 to include the limitation that the surface-altering agent disposed on the surface of the polymer core enhances the average rate at which the particles or a fraction of the particles move in mucus by at least 5-fold compared to the same particles except without a surface-altering agent disposed on the surface. Similarly, Applicants have amended claim 20 to include the limitation that the bioactive agent disposed on the surface of the particle enhances the average rate at which the particles or a fraction of the particles move in mucus by at least 5-fold compared to the same particles except without a bioactive agent disposed on the surface. Support for these amendments can be found on page 5, lines 7-11 of the specification as originally filed. Alavattam does not disclose or teach each and every element of the amended claims. In fact, Alavattam is silent as to the rate of movement of particles through mucus in general, and certainly does not teach the specific details of the 5-fold increase in the average rate at which particles move through mucus, e.g., as recited in the amended claims. Thus, Alavattam does not anticipate the claimed invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection based on 35 U.S.C. § 103(a). Claims 1-2, 5, 7-8, 13, 17, 20, and 21 are rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Alavattam in view of Newman et al. (J. Biomed. Mater. Res., 60: 480-486, 2002; "Newman").

Applicants traverse this rejection to the extent it is maintained over the claims as amended. Neither Alavattam nor Newman teaches or suggests the particles of the claimed invention. Specifically, as discussed above, Alavattam does not teach or suggest all the limitations of the amended claims, such as the 5-fold enhanced average rate of movement through mucus of particles with surface-altering agents or bioactive agents disposed on the surface (as compared to the particles without the surface-altering agents or bioactive agents disposed on the surface). Newman does not make up for the deficiencies of Alavattam. Thus, neither Alavattam nor Newman, alone or in combination, render the claimed invention obvious. Accordingly, Applicants requests reconsideration and withdrawal of this rejection.

Claims 1 and 12 are rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Alavattam in view of Newman and Singh et al. (PNAS, 97(2): 811-816, 2000; "Singh").

Applicants traverse this rejection to the extent it is maintained over the claims as amended. As discussed above, neither Alavattam nor Newman, alone or in combination, render the claimed invention obvious. In particular, neither Alavattam nor Newman, alone or in combination, teach or suggest the 5-fold enhanced average rate of movement through mucus of particles with surface-altering agents or bioactive agents disposed on the surface (as compared to the particles without the surface-altering agents or bioactive agents disposed on the surface), a required limitation of the amended claims. Singh does not cure the deficiencies of Alavattam and Newman. Accordingly, *none* of the cited documents either alone or in any combination teach or suggest the claimed invention. The cited documents thus cannot render obvious the claimed invention. Accordingly, Applicants requests reconsideration and withdrawal of this rejection.

Claims 1 and 18 are rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Alavattam, Newman, and Singh in view of Norris et al. (J. Appl. Poly. Sci., 63: 1481-1492, 1997; "Norris").

Applicants traverse this rejection to the extent it is maintained over the claims as amended. As discussed above, neither Alavattam, Newman, nor Singh, alone or in combination, render the claimed invention obvious since none of the aforementioned documents teach or suggest the 5-fold enhanced average rate of movement through mucus of particles with surface-altering agents or bioactive agents disposed on the surface (as compared to the particles without the surface-altering

agents or bioactive agents disposed on the surface), as recited in the amended claims. Norris does not cure the deficiencies of Alavattam, Newman, and Singh. Accordingly, *none* of the cited documents either alone or in any combination teach or suggest the claimed invention. The cited documents thus cannot render obvious the claimed invention. Accordingly, Applicants requests reconsideration and withdrawal of this rejection.

Claims 1 and 22 are rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Alavattam, Newman, Singh, and Norris in view of Baichwal et al. (U.S. Patent No. 5,612,053; "Baichwal").

Applicants traverse this rejection to the extent it is maintained over the claims as amended. As discussed above, neither Alavattam, Newman, Singh, nor Norris, alone or in combination, render the claimed invention obvious since none of the aforementioned documents teach or suggest the 5-fold enhanced average rate of movement through mucus of particles with surface-altering agents or bioactive agents disposed on the surface (as compared to the particles without the surface-altering agents or bioactive agents disposed on the surface), as recited in the amended claims. Baichwal does not cure the deficiencies of Alavattam, Newman, Singh, and Norris. Accordingly, *none* of the cited documents either alone or in any combination teach or suggest the claimed invention. The cited documents thus cannot render obvious the claimed invention. Accordingly, Applicants requests reconsideration and withdrawal of this rejection.

CONCLUSION

The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Applicants believe we have appropriately provided for fees due with this response. However, if there are any other fees due in connection with filing this submission, please charge our Deposit Account No. 18-1945, under Order No. JHUC-P01-021 from which the undersigned is authorized to draw.

Dated: August 26, 2010

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